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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/258,217 02/26/99 KEATING M 2323-127

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HM22/0103

EXAMINER

CHEN, S

ART UNIT	PAPER NUMBER
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1633

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DATE MAILED:

01/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/258,217

Applicant(s)
Keating et al.

Examiner
Shin-Lin Chen

Group Art Unit
1633



☒ Responsive to communication(s) filed on Oct 25, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-6, 9, and 10 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-6, 9, and 10 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

The amendment filed 10-25-00 has been entered. Claims 1 and 3 have been amended.

Claims 1-6, 9 and 10 are pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1-4 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sechler et al., 1995 (U) in view of Wydner et al., 1994 (X2) and is repeated for the reasons set forth in the

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preceding Official action mailed 7-25-00 (Paper No. 11). Applicant's arguments filed 10-25-00 have been fully considered but they are not persuasive.

Applicants argue that Sechler does not suggest substitution of rat elastin gene with mouse elastin gene and Wydner does not teach a mouse or mouse cell comprising a genome having only one functional elastin gene. Applicants further argue that neither Wydner nor Sechler teaches a mouse or mouse cell having no functional elastin gene. This is not found persuasive because although Sechler or Wydner does not teach all the element in the claims, the collective teachings of Sechler and Wydner do teach all the elements in the claims and provide motivation for combining the teachings of Sechler and Wydner.

Sechler teaches construction of transgenic mice containing rat tropoelastin gene that is either hemizygous ELN +/- or homozygous ELN -/-. Sechler also teaches that there are a variety of disorders characterized by abnormal elastin synthesis and a concomitant deposition of aberrant elastic fiber, such as hypertension, atherosclerosis, actinic elastosis, Marfan's syndrome and SVAS, and mutations in the tropoelastin gene (elastin gene) plays a role in analogous human disorders of elastic tissue, including SVAS (e.g. p. 149). Sechler teaches using the transgenic mice having mutated elastin gene to study the role of elastin gene in analogous human disorder such as SVAS. The mouse embryo stem cell was available at the time of the invention and a method of using embryo stem cell and homologous recombination to generate transgenic mouse was known in the art at the time of the invention. The presence of the mouse elastin cDNA would motivate one of ordinary skill in the art to substitute the rat elastin DNA with mouse

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elastin cDNA to produce transgenic mouse either having hemizygous ELN +/- or homozygous ELN -/- in order to study the function of elastin gene and to study the role of elastin gene in analogous human disorder such as SVAS. Thus, claims 1-4 remain rejected under 35 U.S.C. 103(a) for the reasons set forth above and the reasons set forth in the preceding Official action mailed 7-25-00 (Paper No. 11).

3. Claims 5, 6, 9 and 10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Reitamo et al., 1994 (V) in view of Sechler et al., 1995 (U) and Wydner et al., 1994 (X2) and is repeated for the reasons set forth in the preceding Official action mailed 7-25-00 (Paper No. 11). Applicant's arguments filed 10-25-00 have been fully considered but they are not persuasive.

Applicants argue that the concept taught by Sechler is different from that of the claimed invention and Sechler teaches the coassembling of mutant rat tropoelastin monomer with normal, endogenous mouse tropoelastin instead of the lack of synthesis of wild-type elastin in the claimed invention. This is not found persuasive because of the reasons set forth above and that Reitamo teaches using transgenic mice expressing a human elastin promoter/CAT reporter gene construct for screening a compound which can stimulate the elastin promoter *in vivo* or *in vitro*. Thus, claims 5, 6, 9 and 10 remain rejected under 35 U.S.C. 103(a) for the reasons set forth above and the reasons set forth in the preceding Official action mailed 7-25-00 (Paper No. 11).

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Conclusion

No claims is allowed.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

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Questions of formal matters can be directed to the patent analyst, Kimberly Davis, whose telephone number is (703) 305-3015.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.

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